

Application No. 09/849,611
Response dated October 17, 2005
Reply to Office Action mailed April 27, 2005

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application.

LISTING OF CLAIMS:

1. (Currently Amended) A sustained release composition suitable for use as an excipient for mixing within an orally administered specimen containing a glucosamine-based or other bioactive substance that can irritate the stomach in order to provide a sustained release of the bioactive substance and protect the stomach of a user, comprising:

- (a) powdered cellulose; and
- (b) maltodextrin,

wherein the ratio by weight of the amount of powdered cellulose to the amount of maltodextrin in the sustained release composition is in a range of about 1:9 to about 2:3 such that the amount by weight of the maltodextrin is at least about one and one-half times that of the powdered cellulose, and

wherein, after mixing the sustained release composition with a glucosamine-based or other bioactive substance in an orally administered specimen in an amount so that the powdered cellulose has a concentration in a range from about 4% to about 14% by weight of the orally administered specimen, the powdered cellulose and the maltodextrin act to slow the disintegration of the orally administered specimen to provide a sustained release of the glucosamine-based or other bioactive substance over a period of time of at least in a range of about one hour to about three hours and form a protective gel in order to reduce or eliminate detrimental side effects on the gastrointestinal system of the glucosamine-based or other bioactive substance, break-down products of the bioactive substance, and/or reaction products of the bioactive substance as the specimen breaks down after ingestion by a user.

2. (Previously Presented) A sustained release composition as recited in claim 1, wherein the sustained release composition is suitable for reducing stomach irritation by an orally administered specimen that comprises a glucosamine-based compound.

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3. (Previously Presented) A sustained release composition as recited in claim 1, wherein the sustained release composition is suitable for reducing stomach irritation by an orally administered specimen that comprises a chondroitin-based compound.

4. (Previously Presented) A sustained release composition as recited in claim 1, wherein the sustained release composition is suitable for reducing stomach irritation by an orally administered specimen that comprises methylsulfonyl methane.

5. (Previously Presented) A sustained release composition as recited in claim 1, wherein the sustained release composition is suitable for reducing stomach irritation by an orally administered specimen that comprises a compound selected from the group consisting of glucosamine sulfate, glucosamine hydrochloride, and mixtures thereof.

6. (Previously Presented) A sustained release composition as recited in claim 1, wherein the sustained release composition is suitable for reducing stomach irritation by an orally administered specimen that comprises chondroitin sulfate.

7. (Cancelled)

8. (Currently Amended) A sustained release composition as recited in claim 1, wherein the ratio by weight of the amount of powdered cellulose to the amount of maltodextrin in the sustained release composition is in a range of about 1:4 to about 3:7 such that the amount by weight of the maltodextrin is at least about two and one-third times that of the powdered cellulose.

9. (Cancelled)

10. (Cancelled)

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11. (Previously Presented) A sustained release composition as recited in claim 1, wherein the sustained release composition is suitable for use within an orally administered specimen that is a tablet.

12. (Previously Presented) A sustained release composition as recited in claim 1, wherein said powdered cellulose has a degree of polymerization in a range of about 440 to about 2250.

13. (Previously Presented) A sustained release composition as recited in claim 1, wherein said powdered cellulose has a degree of polymerization of about 1432.

14. (Previously Presented) A sustained release composition as recited in claim 1, wherein said maltodextrin comprises at least one maltodextrin selected from the group consisting of M580 maltodextrin, M700 maltodextrin, and mixtures thereof.

15. (Previously Presented) A sustained release composition as recited in claim 1, wherein said maltodextrin comprises M510 maltodextrin that is substantially free of wheat protein, barley protein, oat protein, and rye protein.

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16. (Previously Presented and Withdrawn) A method for providing sustained release of a bioactive substance during a chosen time interval, comprising:

(a) providing a delivery specimen comprised of the sustained release composition as recited in claim 1 mixed within the delivery specimen together with a bioactive substance;

(b) determining the sustained release of the bioactive substance as a function of time to ascertain the effective amount of bioactive substance that is released and to ascertain the time during which said bioactive substance is released; and

(c) determining a delivery specimen intake frequency and a number of said delivery specimens taken to maintain a desired amount of bioactive substance during a chosen time interval.

17. (Withdrawn) A method as recited in claim 16, wherein said determining the sustained release of the bioactive substance as a function of time comprises determining the cumulative release of the bioactive substance as a function of time.

18. (Withdrawn) A method as recited in claim 16, wherein said determining the sustained release of the bioactive substance as a function of time comprises determining the incremental release of the bioactive substance as a function of time.

19. (Withdrawn) A method as recited in claim 16, wherein said bioactive substance is a compound selected from the group consisting of glucosamine sulfate, glucosamine hydrochloride, and mixtures thereof.

20. (Withdrawn) A method as recited in claim 16, wherein said delivery specimen is a tablet.

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21. (Currently Amended) A sustained release orally administered specimen, comprising:

(a) an excipient portion that includes a sustained release composition mixed throughout the orally administered specimen, the sustained release composition comprising:

powdered cellulose included in an amount in a range of about 4% to about 14% by weight of the orally administered specimen; and

maltodextrin in an amount such that the ratio by weight of the amount of powdered cellulose to the amount of maltodextrin in the orally administered specimen is at least about 1:9 with the proviso that the amount of maltodextrin exceeds the amount of powdered cellulose; and

(b) a bioactive substance mixed with the sustained release composition throughout the orally administered specimen such that the maltodextrin and the cellulose slowly disintegrate when exposed to an aqueous medium to thereby provide a sustained release of the bioactive substance over a time period in a range of at least about one hour to about three hours;

wherein the powdered cellulose and the maltodextrin are mixed with the bioactive substance throughout the orally administered specimen such that, upon ingestion, the sustained release composition gels forms a protective gel to prevent direct contact between at least a portion of the bioactive substance and a stomach wall and reduce or eliminate detrimental side effects on the gastrointestinal system of the bioactive substance, break-down products of the bioactive substance, and/or reaction products of the bioactive substance as the specimen breaks down.

22. (Cancelled)

23. (Previously Presented) A sustained release orally administered specimen as recited in claim 21, wherein said time period is in a range of about one hour to about two hours.

24. (Previously Presented) A sustained release orally administered specimen as recited in claim 21, wherein said bioactive substance comprises a glucosamine-based compound.

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25. (Previously Presented) A sustained release orally administered specimen as recited in claim 21, wherein said bioactive substance comprises a chondroitin-based compound.

26. (Previously Presented) A sustained release orally administered specimen as recited in claim 21, wherein said bioactive substance comprises at least one substance selected from the group consisting of glucosamine sulfate, glucosamine hydrochloride, and mixtures thereof.

27. (Previously Presented) A sustained release orally administered specimen as recited in claim 21, wherein said bioactive substance comprises chondroitin sulfate.

28. (Previously Presented) A sustained release orally administered specimen as recited in claim 21, wherein said bioactive substance comprises methylsulfonyl methane.

29. (Previously Presented) A sustained release orally administered specimen as recited in claim 21, wherein said powdered cellulose is included in an amount by weight in the orally administered specimen in a range of about 5% to about 13%.

30. (Previously Presented) A sustained release orally administered specimen as recited in claim 21, wherein the cumulative sustained release of the bioactive substance as a function of time increases for a time period of at least about one hour.

31. (Previously Presented) A sustained release orally administered specimen as recited in claim 21, wherein the incremental sustained release of the bioactive substance as a function of time provides an amount of the bioactive substance that is, in any fifty-minute interval during said time period, less than about 50% of the total amount of the bioactive substance initially present in the orally administered specimen.

32. (Previously Presented) A sustained release orally administered specimen as recited in claim 21, wherein said orally administered specimen is a tablet.

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33. (Currently Amended) A sustained release orally administered specimen, comprising:

(a) an excipient portion that includes a sustained release composition mixed throughout the orally administered specimen, the sustained release composition comprising:

powdered cellulose included in an amount by weight of the orally administered specimen in a range of about 4% to about 14%; and

maltodextrin in an amount such that the ratio by weight of the amount of powdered cellulose to the amount of maltodextrin in the orally administered specimen is at least about 1:9 with the proviso that the amount of maltodextrin exceeds the amount of powdered cellulose; and

(b) a glucosamine-based substance mixed with the sustained release composition throughout the orally administered specimen such that the maltodextrin and the cellulose slow the disintegration of the orally administered specimen and thereby provide in an aqueous medium a sustained release of the glucosamine-based substance for a time interval such that the released glucosamine-based substance does not significantly irritate a recipient's stomach lining as the specimen breaks down in the stomach;

wherein the powdered cellulose and the maltodextrin are mixed with the glucosamine-based substance throughout the orally administered specimen such that, upon ingestion, the sustained release composition gels forms a protective gel to prevent direct contact between at least a portion of the glucosamine-based substance and a stomach wall and thereby acts as a stomach guard with respect to the glucosamine-based substance as the specimen breaks down in the stomach.

34. (Previously Presented) A sustained release orally administered specimen as recited in claim 33, wherein said maltodextrin is a commercial maltodextrin free from wheat protein, barley protein, oat protein, and rye protein.

35. (Previously Presented) A sustained release orally administered specimen as recited in claim 33, wherein said specimen is a tablet.

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36. (Previously Presented) A sustained release orally administered specimen as recited in claim 33, wherein said powdered cellulose is included in an amount by weight in the orally administered specimen in a range of about 5% to about 13%.

37. (Currently Amended) A sustained release orally administered specimen as recited in claim 33, wherein the ratio by weight of the amount of powdered cellulose to the amount of maltodextrin in the orally administered specimen is in a range of about 1:9 to about 2:3 such that the amount by weight of the maltodextrin is at least about one and one-half times that of the powdered cellulose.

38. (Currently Amended) A sustained release orally administered specimen as recited in claim 33, wherein the ratio by weight of the amount of powdered cellulose to the amount of maltodextrin in the orally administered specimen is in a range of about 1:4 to about 3:7 such that the amount by weight of the maltodextrin is at least about two and one-third times that of the powdered cellulose.

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39. (Currently Amended and Withdrawn) A method for providing sustained release of a bioactive substance during a chosen time interval, comprising:

- (a) providing a sustained release orally administered specimen delivery specimen that comprises a sustained release composition as recited in claim 20 ~~1~~ mixed with a bioactive substance throughout the delivery specimen;
- (b) determining the sustained release of the bioactive substance as a function of time to ascertain the effective amount of bioactive substance that is released and to ascertain the time during which said bioactive substance is released; and
- (c) determining an intake frequency and a number of said delivery specimens to maintain a desired amount of bioactive substance during a chosen time interval.

40. (Withdrawn) A method as recited in claim 39, wherein said determining the sustained release of the bioactive substance as a function of time comprises determining at least one of the cumulative release of the bioactive substance as a function of time and the incremental release of the bioactive substance as a function of time.

41. (Previously Presented and Withdrawn) A method as recited in claim 39, wherein said maltodextrin comprises at least one maltodextrin selected from the group M510 maltodextrin, M580 maltodextrin, M700 maltodextrin, and mixtures thereof.

42. (Previously Presented and Withdrawn) A method as recited in claim 39, wherein the powdered cellulose is included in an amount by weight in the delivery specimen in a range of about 5% to about 13%.

43. (Currently Amended and Withdrawn) A method as recited in claim 39, wherein the delivery specimen is a tablet, and the ratio by weight of the amount of powdered cellulose to the amount of maltodextrin in the delivery specimen is in a range of about 1:4 to about 3:7 such that the amount by weight of the maltodextrin is at least about two and one-third times that of the powdered cellulose.